

RUPANASE[®] Junior

SCHEDULING STATUS

[S2]

RUPANASE JUNIOR contains Rupatadine 1mg/ml oral solution

CONTAINS SUGAR: Sucrose 300 mg/ml

CONTAINS SWEETENER: Saccharin sodium 0,5 mg/ml

Read all of this leaflet carefully because it contains important information for you

RUPANASE JUNIOR is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use **RUPANASE JUNIOR** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **RUPANASE JUNIOR** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 28 days.

What is in this leaflet

1. What **RUPANASE JUNIOR** is and what it is used for
2. What you need to know before you use **RUPANASE JUNIOR**
3. How to use **RUPANASE JUNIOR**
4. Possible side effects
5. How to store **RUPANASE JUNIOR**
6. Contents of the pack and other information

1. What **RUPANASE JUNIOR** is and what it is used for

RUPANASE JUNIOR contains the active ingredient rupatadine which is an antihistamine. **RUPANASE JUNIOR** is used to relieve symptoms of allergic rhinitis (including persistent allergic rhinitis), urticaria and itching in the eyes and nose in children aged 2 to 11 years and weighing 10 kg or more.

2. What you need to know before you use **RUPANASE JUNIOR**

Do not use **RUPANASE JUNIOR**:

- If you are hypersensitive (allergic) to rupatadine or any of the other ingredients of **RUPANASE JUNIOR** (listed in section 6).
- For children below 2 years of age, or weighing less than 10 kg.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with **RUPANASE JUNIOR**:

- If you have kidney or liver insufficiency, ask your doctor for advice. The use of **RUPANASE JUNIOR** is not recommended in patients with impaired kidney or liver functions.
- If you have low blood levels of potassium and/or if you have a certain abnormal pattern to your heartbeat (known prolongation of the QTc interval on the ECG) which can occur in some forms of heart disease, ask your doctor for advice.
- If you are older than 65 years, ask your doctor or pharmacist for advice.

Other medicines and **RUPANASE JUNIOR**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are taking **RUPANASE JUNIOR** do not take medicines containing ketoconazole (antifungal) or erythromycin (antibiotic).

RUPANASE JUNIOR should be used with caution when you are on statin containing medicine for high cholesterol, or any central nervous system depressant medicine.

RUPANASE JUNIOR with food and drink

Can be taken with or without food and drink.

Avoid the intake of grapefruit juice along with **RUPANASE JUNIOR**

It is not advisable to use alcohol concomitant with **RUPANASE JUNIOR**

Pregnancy, breastfeeding and fertility

The use of **RUPANASE JUNIOR** is contraindicated during pregnancy. As rupatadine is excreted in animal milk and due to the potential harmful effects in neonates, the use of **RUPANASE JUNIOR** should be avoided during breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

At the recommended dosage, **RUPANASE JUNIOR** is not expected to influence your ability to drive or use machinery.

However, it is not always possible to predict to what extent **RUPANASE JUNIOR** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **RUPANASE JUNIOR** affects them.

RUPANASE JUNIOR contains sucrose and methyl parahydroxybenzoate

Sucrose, a sugar, may be harmful to the teeth. If you have rare hereditary problems of fructose intolerance, glucose/galactose malabsorption or sucrose-isomaltase insufficiency, you should not take this medicine.

RUPANASE JUNIOR contains sucrose which may have an effect on the control of your blood sugar if you have *diabetes mellitus*.

This medicine also contains methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to take **RUPANASE JUNIOR**

Do not share medicines prescribed for you with any other person.

Always take **RUPANASE JUNIOR** exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Children aged 2 to 11 years:

- *Children weighing equal to or more than 25 kg:*
Give 5 mL once a day, with or without food.
- *Children weighing equal to or more than 10 kg up to less than 25 kg:*
Give 2,5 mL once a day, with or without food.

Not recommended for children under 2 years of age.

RUPANASE JUNIOR should be used with caution in elderly people.

In adults and adolescents (over 12 years of age), the administration of rupatadine 10 mg tablets is more appropriate.

Your doctor will tell you how long your treatment with **RUPANASE JUNIOR** will last.

If you have the impression that the effect of **RUPANASE JUNIOR** is too strong or too weak, tell your doctor or pharmacist.

Instructions for use:



- To open the bottle, press the cap and turn it anticlockwise.



- Take the syringe and put it in the perforated stopper and turn the bottle upside down.



- Fill the syringe with the prescribed dose.



- Administer directly from the dosing syringe.



- Wash the syringe after use.

If you take more **RUPANASE JUNIOR** than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take **RUPANASE JUNIOR**

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with **RUPANASE JUNIOR** is stopped

Your symptoms of your allergy may become worse or return if you stop your treatment.

4. Possible side effects

RUPANASE JUNIOR can have side effects.

Not all side effects reported for **RUPANASE JUNIOR** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **RUPANASE JUNIOR**, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent side effects:

- headache,
- somnolence (sleepiness).

Less frequent side effects:

- influenza (flu),
- nasopharyngitis (common cold),
- upper respiratory tract infection (infection of the upper airways),
- eosinophilia or neutropenia (abnormal counts of white blood cells in the blood),
- dizziness,
- nausea,
- eczema (red, itchy skin condition),
- night sweats
- fatigue (feeling tired).

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form" found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/index/8>. By reporting side effects, you can help provide more information about the safety of **RUPANASE JUNIOR**.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000. Website: www.inovapharma.co.za.

5. How to store **RUPANASE JUNIOR**

Keep all medicines out of the reach and sight of children.

Store at or below 30 °C.

Keep the bottle in the carton until required for use.

Keep the bottle tightly closed.

Do not refrigerate.

Shake the bottle before use.

Do not store in a bathroom.

Do not use **RUPANASE JUNIOR** after the expiry date stated on the bottle and carton. The expiry date refers to the last day of that month. The shelf life after first opening is the same as the expiry date stated on the bottle and carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What **RUPANASE JUNIOR** contains

- The active substance is rupatadine in a concentrate of 1 mg rupatadine base per 1 mL solution.
- The other ingredients are methyl parahydroxybenzoate 0,1 % w/v, banana flavour (a blend of natural identical flavouring substances, flavouring preparations and propylene glycol), citric acid anhydrous, disodium phosphate anhydrous, propylene glycol, purified water, sucrose, saccharin sodium, Quinoline Yellow E104 (pure dye, monosulfonated colour, disulfonated colour, trisulfonated colour).

What **RUPANASE JUNIOR** looks like and contents of the pack

Clear yellow oral solution with the smell and flavour of bananas.

RUPANASE JUNIOR is packaged in an amber plastic (PET) bottle with a perforated (LDPE) stopper and a yellow (HDPE) child-resistant cap. The bottle, containing 120 mL solution, is packed in an outer carton also containing a 5 mL two-piece oral syringe, consisting of a transparent polypropylene barrel and a transparent HDPE plunger, graduated at 0,25 mL.

Holder of the Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007

Telephone number: +27 11 087 0000

Website: www.inovapharma.co.za.

This leaflet was last revised in: 19 June 2020.

Registration number: 50/5.7.1/0569

Access to the corresponding Professional Information for healthcare professionals

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals

NAMIBIA: NS1 17/5.7.1/0042

BOTSWANA: S3 BOT1703031

ZIMBABWE: 2018/5/5767
PRESCRIPTION PREPARATION (P.P)

